REMARKS

In view of the above amendments and following remarks, reconsideration and further examination are requested.

Claims 34-47 were rejected under 35 U.S.C §112, second paragraph, as being indefinite for a variety of reasons. In order to address many of the 35 U.S.C §112, second paragraph, concerns, claims 34-47 have been amended. However, two of the 35 U.S.C §112, second paragraph, issues raised by the Examiner have not been addressed by amending the claims, but are rather discussed as follows.

First, the following discussion is provided with regard to the Examiner's position that the claims are unclear as to what exactly is involved in the claimed "correcting" step.

Basically, the present invention provides for correcting a bonding amount of the marker reagent measured in the second measuring step based on the total amount of marker reagent (a relationship between a theoretical total amount and an actual total amount) involved in this measurement. In the field of biosensors, performance varies for every lot even if the same materials and processes are used. Therefore, generally, biosensors of one lot are shipped after a calibration curve (regression formula) is determined. However, due to factors such as elapsed time and external environments experienced during shipping, results which are obtained from the same density inspection target solution may be different even when using biosensors of the same lot.

The present invention claims to perform a correction with high accuracy by detecting the total amount of a marker reagent which relates to a reaction at a measurement by a user. To perform this kind of correction, an optimal value based on a manufacturing lot is required, and individual values are shown in the embodiments.

The reason for generally claiming "correcting" is that there are various possible patterns for this correction, such as:

1) subtraction (an amount of the marker reagent initially placed on the sensor minus an eluted amount of the marker reagent);

2) proportion (an eluted amount of the marker reagent divided by an amount of the marker reagent initially placed on the sensor); and

3) proportion (the initial total eluted amount of the lot of the sensor divided by the total eluted amount detected during measurement).

Therefore, the basic concept of "correcting" means a step in which a correction is performed based on the total amount of the marker reagent related to a reaction by using an eluted amount of the marker reagent or residual eluted amount. One having ordinary skill in the art would fully be able to ascertain the scope of the claims without more specifically reciting what is involved in the "correcting" step.

Second, with regard to the Examiner's position that claims 38 and 45 are confusing because of the recitation of "part of said marker reagent being elutable", the following discussion with regard to the 35 U.S.C §112, first paragraph, rejection, is believed to make it clear as to why this language would not be confusing to one having ordinary skill in the art.

Claims 38 and 45 were rejected under 35 USC §112, first paragraph, for containing new matter. This rejection is respectfully traversed for the following reasons.

Claims 38 and 45 are based on descriptions in the original specification at page 16, lines 4-11, page 24, line 20 - page 25, line 10, Figure 2(c), Figure 6(a), and Figure 6(b). These claims are characterized in measuring a residual amount of the marker reagent eluted from a first part (2) of a development portion at a part (8) of the development portion, and correcting the amount of marker reagent that is bonded to a second part (7) of the development portion based on the relationship between the amount of the residual marker reagent measured at part (8) and the total amount of the marker reagent that is held preliminarily in first part (2).

In this rejection of claims 38 and 45, the Examiner states that

> claims 38 and 45 recite methods using biosensors where marker reagents are held in a first part of a development portion such that **only** part of said marker reagent are elutable by a test sample.

It is respectfully submitted that this is a mis-characterization of what is actually recited by claims 38 and 45. In this regard, the marker reagent held in the development portion is not held such

that "only" a portion of the marker reagent can be eluted by the inspection target solution. Rather, with the instant invention the marker reagent held in the first development portion is measured, i.e. that portion of the marker reagent which is not eluted even when the inspection target solution is developed.

To further explain what is intended by claims 38 and 45, the following is provided.

As described in the specification, in the conventional method which measures a measurement target in an inspection target solution by detecting the bonding amount of marker reagent at the antibody immobilization part of a sensor, the elution amount of the marker reagent varies due to factors including a dry state of the sensor, a preservation condition of a reagent in the sensor, temperature, humidity, fabrication time in manufacturing the sensor, deterioration with age from start of fabrication, factors pertaining to properties of the inspection target solution, and factors pertaining to measuring operations such as erroneous operations or environments during measurement.

While the measurement of a bonding amount of a marker reagent in an antibody immobilization part can be performed more accurately and uniformly when the elution amount of the marker reagent is constant, when the elution amount of the marker reagent varies due to the aforementioned factors, the amount of the marked antibody which is bonded to the antibody immobilization part for each measurement varies even when the concentration of the measurement target in the inspection target solution is constant. Thus, in a case where the elution amount of the marker reagent varies due to the aforementioned factors, when a measurement for obtaining a qualitative measurement result is implemented, an erroneous measurement result is given especially in the vicinity of a high sensitivity measurement limit, and also when the elution amount of the marker reagent is extremely small.

Thus, while all of the marker reagent of a biosensor will elude in theory, such may not actually be the case after shipment due to the aforementioned external factors. Therefore, using a biosensor after having been kept in various unpredictable environments, as in the case of using a biosensor immediately after manufacturing, using a biosensor when a guarantee period nearly

expires, and using a biosensor after being kept under a severe condition, must be fully considered by a manufacturer.

Furthermore, generally in POCT (Point-Of-Care-Testing), which is a clinical field of the present invention, users do not posses scientific knowledge in many cases, and therefore, it is necessary to presume that just confirming the results might become a serious problem. This is especially true when giving an erroneous result of a clinical measurement might influence one's life. The present invention allows users who lack scientific knowledge to safely achieve accurate results.

In view of the above, it is respectfully submitted that claims 34-47 are in full compliance with 35 U.S.C §112, first and second paragraphs, whereby the present application is in condition for allowance and an early Notice of Allowance is earnestly solicited.

If after reviewing this Amendment, the Examiner believes that any issues remain which must be resolved before the application can be passed to issue, the Examiner is invited to contact the Applicants' undersigned representative by telephone to resolve such issues.

Respectfully submitted,

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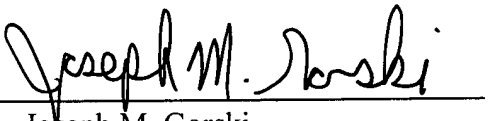
By: 

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